



1/16 DAC

PATENT
ATTORNEY DOCKET NO. 50195/023003

Certificate of Mailing: Date of Deposit: December 1, 2008

I hereby certify under 37 C.F.R. § 1.8(a) that this correspondence is being deposited with the United States Postal Service as **first class mail** with sufficient postage on the date indicated above and is addressed to Mail Stop Petition, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

Joseph Povec

Printed name of person mailing correspondence

Joseph C. Povec

Signature of person mailing correspondence

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant:	Robl et al.	Confirmation No.:	4828
Patent No.	7,429,690	Art Unit:	1632
Serial No.:	10/705,519	Examiner:	Deborah Crouch
Filed:	November 10, 2003	Customer No.:	21559
Issued:	September 30, 2008		
Title:	TRANSGENIC BOVINES HAVING REDUCED PRION PROTEIN PRODUCTION		

Mail Stop Petition
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

PETITION FOR RECONSIDERATION
OF PATENT TERM ADJUSTMENT UNDER 37 C.F.R. § 1.705

In response to the Determination of Patent Term Adjustment under 35 U.S.C. § 154(b) set forth on the Issue Notification mailed on September 30, 2008 in connection with the above-captioned patent application, Applicants hereby request reconsideration of the patent term adjustment. Applicants submit that the correct total Patent Office delay is 661 days, and therefore the total patent term adjustment should be 469 days (i.e., total Patent Office delay of 661 days minus total Applicant delay of 192 days). Applicants discuss the basis for this request below.

12/04/2008 EFLORES1 00000001 7429690

01 FC:1455

200.00 OP

Background Law and Rules

35 U.S.C. § 154(b)(1)(A) states:

Subject to the limitations under paragraph (2), if the issue of an original patent is delayed due to the failure of the Patent and Trademark Office to-

(i) provide at least one of the notifications under section 132 of this title or a notice of allowance under section 151 of this title not later than 14 months after-

the date on which an application was filed under section 111(a) of this title;

* * *

the term of the patent shall be extended 1 day for each day after the end of the period specified in clause (i), (ii), (iii), or (iv), as the case may be, until the action described in such clause is taken.

Corresponding provisions are found in 37 C.F.R. §§ 1.702(a)(1) and 1.703(a)(1).

Applicants refer to Office delay under 35 U.S.C. § 154(b)(1)(A), and the corresponding rules, as “A delay.”

35 U.S.C. § 154(b)(1)(B) states:

Subject to the limitations under paragraph (2), if the issue of an original patent is delayed due to the failure of the United States Patent and Trademark Office to issue a patent within 3 years after the actual filing date of the application in the United States, not including-

(i) any time consumed by continued examination of the application requested by the applicant under section 132(b);

* * *

the term of the patent shall be extended 1 day for each day after the end of that 3-year period until the patent is issued.

Corresponding provisions are found in 37 C.F.R. §§ 1.702(b)(1) and 1.703(b)(1).

Applicants refer to Office delay under 35 U.S.C. § 154(b)(1)(B), and the corresponding rules, as “B delay.”

35 U.S.C. § 154(b)(2)(A) states (emphasis added):

To the extent that periods of delay attributable to grounds specified in paragraph (1) overlap, the period of any adjustment granted under this subsection shall not exceed the actual number of days the issuance of the patent was delayed.

A corresponding provision is found in 37 C.F.R. § 1.703(f).

The Office has explained its interpretation of the “overlap” provisions of 35 U.S.C. § 154(b)(2)(A) and 37 C.F.R. § 1.703(f) as follows (emphasis added):

[T]he Office has consistently taken the position that if an application is entitled to an adjustment under the three-year pendency provision of 35 U.S.C. 154(b)(1)(B), the entire period during which the application was pending before the Office (except for periods excluded under 35 U.S.C. 154 (b)(1)(B)(i)-(iii)), and not just the period beginning three years after the actual filing date of the application, is the relevant period under 35 U.S.C. 154 (b)(1)(B) in determining whether periods of delay “overlap” under 35 U.S.C. 154(b)(2)(A).

Explanation of 37 CFR 1.703(f) and of the United States Patent and Trademark Office Interpretation of 35 U.S.C. 154(b)(2)(A), 69 Fed. Reg. 34283, 34283 (Jun. 21, 2004).

However, the Office’s interpretation was recently rejected by the U.S. District Court for the District of Columbia, which stated (emphasis added):

The operative question under 35 U.S.C. § 154(b)(2)(A) is whether “periods of delay attributable to grounds specified in paragraph (1) overlap.” The only way that periods of time can “overlap” is if they occur on the same day. If an “A delay” occurs on one calendar day and a “B delay” occurs on another, they do not overlap, and § 154(b)(2)(A) does not limit the extension to one day. Recognizing this, the PTO defends its interpretation as essentially running the “period of delay” under sub-section (B) from the filing date of the patent

application, such that a period of “B delay” *always overlaps* with any periods of “A delay” for the purposes of applying § 154(b)(2)(A).

The problem with the PTO’s construction is that it considers the application *delayed* under § 154(b)(1)(B) during the period *before it has been delayed*. That construction cannot be squared with the language of § 154(b)(1)(B), which applies “if the issue of an original patent is *delayed* due to the failure of the United States Patent and Trademark Office to issue a patent within 3 years.” (Emphasis added.) “B delay” begins when the PTO has failed to issue a patent within three years, not before.

Wyeth v. Dudas, No. 07-1492 (JR), 2008 U.S. Dist. LEXIS 76063, at *3 (D.D.C. Sept. 30, 2008).

Accordingly, Applicants submit that, where A delay occurs entirely before the three-year date, and thus does not overlap the period of B delay, the periods of A delay and B delay are not to be considered overlapping under § 154(b)(2)(A), but rather must be added together to determine the overall Office delay.

The ‘690 Patent

Applicants submit that the Patent Office B delay under 35 U.S.C. § 154(b)(1)(B) for failure to issue a patent within three years after the filing date of the application of 206 days should be added to the previously calculated Patent Office A delay under 35 U.S.C. § 154(b)(1)(A) of 455 days to yield a correct total Patent Office delay of 661 days.

Applicants filed the above-referenced application on November 10, 2003. The difference between November 10, 2006 (i.e., the date that is three years after the filing date of the application) and June 4, 2007 (i.e., the date of receipt by the U.S. Patent and Trademark Office of a Request for Continued Examination) is 206 days and therefore, the Patent Office B delay under 35 U.S.C. § 154(b)(1)(B) is 206 days.

Applicants submit that the Patent Office A delay under 35 U.S.C. § 154(b)(1)(A) was correctly calculated: 455 days for failure to mail a notification under 35 U.S.C. § 132 or a notice of allowance under 35 U.S.C. § 151 within 14 months of the filing date of the application. The 14-month deadline was January 10, 2005, and the first notification under 35 U.S.C. § 132 was mailed April 10, 2006, thus a delay of 455 days.

Likewise, based on an analysis of 37 C.F.R. § 1.704, Applicants agree with the Office's calculation that the total applicant delay is 192 days.

U.S.C. § 154(b)(2)(A) specifies that "the periods of delay attributable to grounds specified in paragraph (1) overlap, the period of any adjustment granted under this subsection shall not exceed the actual number of days the issuance of the patent was delayed."

The U.S. Patent and Trademark Office has previously interpreted U.S.C. § 154(b)(2)(A) to mean that any calculated delays under U.S.C. § 154(b)(1)(A) and U.S.C. § 154(b)(1)(B) (A delay and B delay, respectively) may not be added together, despite the fact that the days encompassed by each delay were not the same *calendar days*.

However, in Wyeth, the U.S. District Court for the District of Columbia stated that *unless* delays under U.S.C. § 154(b)(1)(A) and U.S.C. § 154(b)(1)(B) (A delay and B delay, respectively) did, in fact, overlap the same *calendar days*, they should be added together to calculate the total Patent Office delay. Id.

Consistent with Wyeth, as the Patent Office A delay under 35 U.S.C. § 154(b)(1)(A) of 455 days (January 10, 2005 to April 10, 2006) and the Patent Office B delay under 35 U.S.C. § 154(b)(1)(B) of 206 days (November 10, 2006 to June 4, 2007) do not encompass overlapping calendar days, they should be added to provide a total Patent Office delay of 661 days (445 days + 206 days = 661 days). Id. In light of this requested correction of total Patent Office delay, Applicants submit that the correct total

Patent Term Adjustment should be 469 days (661 days of total Patent Office delay - 192 days of total Applicant delay = 469 days), and such correction is also hereby respectfully requested.

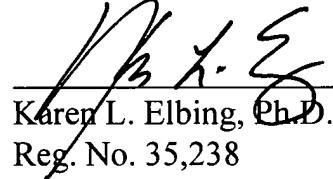
CONCLUSION

For the above reasons, Applicants submit that the current patent term adjustment should be 469 days and request reconsideration of the patent term adjustment. The present patent is not subject to a terminal disclaimer.

Enclosed is a check in the amount of \$200.00 for the fee set forth in 37 C.F.R. § 1.18(e). If there are any additional charges or any credits, please apply them to Deposit Account No. 03-2095.

Respectfully submitted,

Date: 01 December 2008


Karen L. Elbing, Ph.D.
Reg. No. 35,238

Clark & Elbing LLP
101 Federal Street
Boston, MA 02110
Telephone: 617-428-0200
Facsimile: 617-428-7045